IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFF'S RESPONSE TO DEFENDANT'S MOTION TO QUASH AND CROSS-MOTION TO EXPAND AND DEFINE THE SCOPE OF DISCOVERY

Plaintiffs respectfully move: (1) that this court reconsiders its order to stay the subpoena Plaintiffs issued to Gibraltar Laboratories, Inc. ("Gibraltar"), and (2) that the scope of discovery in this case be expanded and defined to include as relevant and discoverable information relating to all products manufactured at the Actavis Totowa LLC, Little Falls facility. Based on the closely intertwined manufacturing processes of the Little Falls facility, and warnings from the Federal Food and Drug Administration that state the same, a systematic problem existed at said facility that affected all products produced, including Digitek®. Since these other production processes are relevant, the scope of discovery should be expanded to include all products made at the aforementioned facility, and as such the subpoena to Gibraltar is proper as it was submitted and should not be stayed. In the alternative, if the court should rule that the scope of discovery should not be extended and that Plaintiffs' subpoena should be stayed, Plaintiffs respectfully ask that the court be allowed to view the original disputed documents produced by Gibraltar pursuant to the subpoena prior to redaction to review the documents for any potential privilege.

A Brief in response to Defendant's Motion and in Support of Plaintiff's Motion is attached.

PLAINTIFF'S BRIEF IN SUPPORT OF IT'S RESPONSE TO DEFENDANT'S MOTION TO QUASH AND CROSSMOTION TO EXPAND AND DEFINE THE SCOPE OF DISCOVERY

FACTS

On February 5, 2009 Judge Joseph R. Goodwin entered Pretrial Order ("PTO") #12 (Ex. A) which serves as a stipulated protective order in this litigation. Within this order, provisions are made for the treatment of confidential information which is defined as any piece of information the Supplying Party in "good faith" believes should be afforded protection under Rule 26(c) of the Federal Rules of Civil Procedure. (Ex. A ¶ II(A)). The PTO also includes provisions as to what is considered as confidential and may be subject to redaction by the Supplying Party including, "any information relating to products other than Digitek®, unless manufacturing information about a product other than Digitek® is reasonably related to Digitek® manufacturing." (*See* Ex. A at ¶ II (F)(4)).

In accordance with PTO #16 Plaintiffs took several Rule 30(b)(6) depositions of agents appointed by the Defendant to discuss organizational and structural matters pertaining to the Little Falls facility. James Fitzpatrick, the Director of Human Resources for the US-Solid Oral Dose Division[1], was designated by Actavis as the corporate representative for the overall organization and structure. During his deposition Mr. Fitzpatrick opined that there is no set organization as to who is in charge of manufacturing certain drugs, and that there is often times a mixing of responsibilities for multiple drugs to one person for production purposes. (Ex. B Fitzpatrick Dep. 135:20-138:11, May 20, 2009). In fact Mr. Fitzpatrick went on to say that he is "not aware of anybody [that is] in charge of a product line." (*See* Ex. B at 140:19-20). There is

[1] Mr. Fitzpatrick works for the US-SOD division which encompasses Actavis Totowa LLC and Actavis Elizabeth LLC. (Ex. B, 61:17-62:10). He began working for "Actavis" on March 31, 2008. He receives his paycheck from Actavis Elizabeth LLC and works primarily out of the Actavis Inc. headquarters in Morristown, New Jersey. (Ex. B. 63:12-64:10; 80:17-81:4).

no "individual who's charged with the responsibility for overseeing [the Digitek®] product line….Someone isn't responsible for the production of Digitek®. Someone's responsible for the production of all the products…[A] department is responsible within their function for all 104 products" (Ex. B, 136:21- 137:14). The assertion that Actavis personnel would be assigned multiple responsibilities for manufacturing of several products is confirmed in the Deposition of Anthony Delicato[2] (Ex. C). Mr. Delicato testified that employees are not broken down by product lines. There is no Digitek® Supervisor; instead a given supervisor is in charge the medication that happens to be on the production schedule for that supervisor's defined manufacturing area. (Ex. C 49:7-51:1; 54:3-56:10) "On a given day, [a supervisor] would be in charge of multiple products. … [I]t could be two products, it could be five products. It's whatever the schedule required and the availability of the equipment" allows. (Ex. C. 50:19-51:1). For example, everything that requires "tableting" would be supervised by one of two tableting supervisors and handled by one or more of the fifteen operators in that area.[3] (Ex. C, 59:10-19). There is no "effort to have a dedicated single person and single chain of command for a product line, for a single product." (Ex. C. 59:20-24). Mr. Delicato also noted that the same set of machines is used to make different products.(Ex. C 70; 1-3). Further, Mr. Delicato suggested that quality control is handled for all product lines by the same group of employees with no specialization as to product. (*See* Ex. C at 96:9-18).

[2] Prior to May, 2008, Mr. Delicato was the Site Director for Quality Assurance at Actavis Elizabeth LLC and he did not have any responsibilities at Actvis Totowa LLC. (Ex. C, 28:19-30:24) In May, 2008, he was promoted to Quality Assurance Director for New Jersey Solid Oral Dose Operations which includes Actavis Totowa LLC. (Ex. C. at 29:10-30:7). Mr. Delicato's understanding of Actavis Totowa is from conversations with Phyllis Lambridis, organizational charts and conversations with employees during his transition in 2008. (Ex. C. 35:12-36:24). His knowledge of the quality division at Totowa is limited to the same information and his background in the quality department at Actavis Elizabeth LLC.

[3] See the Floor Plan for the Little Falls Facility, attached as Exhibit D, for manufacturing areas.

The warning letters from the U.S. Food and Drug Administration (FDA) to Defendant Actavis Totowa LLC, give examples of the manufacturing process and general procedures at the Little Falls facility that were outside of FDA regulations. In the first letter sent August 15, 2006 (Ex. E), the FDA stated that there were a number of manufacturing violations occurring at the facility and the violations were, "serious and may be symptomatic of underlying problems." (Ex. E at Sec. 5 ¶ 2). The FDA also warned of violations of adverse medical event reporting obligations, and marketed drugs that did not have proper clearance. According to the FDA's August 2006 Warning Letter, an FDA inspection in early 2006 revealed that there were six (6) potentially serious and unexpected adverse drug events relating back to 1999 for products, including Digitek®, that were not properly reported to the agency. (Ex. E at Sec. 1 ¶ 1). The letter went on to warn about not properly investigating serious and unexpected ADEs, not adequately reviewing ADE information, failing to develop proper procedures for surveillance, receipt, evaluation and reporting of ADEs and failing to file periodic safety reports which resulted in at least twenty-six (26) unreported ADEs. (Ex. E at Sec. 2-5).

A second warning letter was sent to Actavis Totowa from the FDA on February 1, 2007. (Ex. F). This letter immediately lays out that inspectors observed, "significant deviations from the current Good Manufacturing Practice regulations". (Ex. F at ¶ 1). A major complaint listed is that the quality control department was not up to standards and that there is "no assurance" that "many products" have the proper strength, identity, quality and purity that they are suppose to have under the specifications stated by Actavis Defendants. (Ex. F Sec. 1 ¶ 1). The letter further opined that many times the quality control unit failed to address issues with manufacturing deviations from in-process specifications. (*Id.* at ¶ 3). The letter enumerated several product lines that were not up to specifications for hardness, and impurities. (Ex. F). Furthermore, the

letter noted that several batches, rejected for not being up to standards, were held in an "in progress products warehouse" and could end up in the stream of commerce. (Ex. F at Sec. 6). Finally, the letter stated that problems with the cleaning of machines between batches of different drugs existed for several products including Digoxin. (Ex. F at Sec. 7(a)).

On May 4, 2009 Plaintiffs issued a Third-Party Subpoena commanding Gibraltar Laboratories to produce documents that may contain information that relates to Digitek® as well as other products produced by the Defendants that Gibraltar may have in its possession. Just days prior to the scheduled production of records to the Plaintiff, Defendant moved to quash the aforementioned subpoena on June 4, 2009. The Motion to Quash occurred after the Defendants attempted to invoke that they were the supplying party of the information in their contractual relationship with Gibraltar and as such should be able to redact information as privileged. On June 4, 2009 Judge Mary E. Stanley issued an order staying Plaintiff's subpoena.

ARGUMENT

A. The stay on Plaintiff's subpoena should be lifted because Defendants are not entitled to unilaterally redact information from a third party under the rules set forth in the Protective Order.

The Protective Order clearly states what procedures are to be taken when obtaining information by a third party that could be protected. In the current instance Defendant seeks to circumvent the Protective Order by claiming that based on a contract, they are in fact the Original Supplying Party and that as such they can unilaterally redact information. The Protective Order states that other product lines' manufacturing information that is reasonably related to Digitek® manufacturing is NOT protected as confidential information and is discoverable. The information from the deponents strongly suggests fact the manufacturing of Digitek® was affected in much the same way as other drugs because of the intermingling of staff

and equipment at all levels from the production line to the quality control unit. Additionally, if the production is intermingled there is a reasonable assertion that the manufacturing techniques and underlying problems that were laid out by the FDA warning letters, could reasonably relate to the manufacturing of Digitek®. The Plaintiffs assert below that the manufacturing processes of the Defendant are intertwined and in many cases indistinguishable amongst product lines, and as such information that Gibraltar has pertaining to one product line could reasonably affect Digitek® and should be discoverable. For these reasons the subpoena issued to Gibraltar was proper.

B. Discovery should be expanded to include all manufacturing processes of the Little Falls facility for all product lines because good cause exists that such information is relevant to the current litigation.

Good cause exists to broaden the scope of discovery in the present case to include all manufacturing processes at the Actavis Totowa facility in Little Falls. Plaintiffs agreed to the Stipulated Protective Order, PTO # 12, based upon Defendants' representations that Digitek® was a separate, independent product line, differentiated within the Little Falls plant from all other product lines. Plaintiffs had no information relating to the actual manner of production within the Little Falls plant, and agreed to defer broader discovery until they gained insight into the actual design and process of manufacture within the plant. Having now conducted 30(b)(6) depositions, and having been able to review some documentary discovery, Plaintiffs are shocked to discover the extent of comingling between product lines within the plant. There is no way to separate out the Digitek® product line from that of any of the other 105 product lines manufactured contemporaneously at the Little Falls plant. All equipment and all personnel were interchangeably utilized to manufacture all products.

The rules of discovery are to be given a broad and liberal treatment. *Taggart v. Damon Motor Coach*, 2007 U.S. Dist. LEXIS 3462, 6 (N.D.W Va. 2007) (citing *Nat'l Union Fire Ins. Co. of Pittsburgh, P.A. v. Murray Sheet Metal Co. Inc.*, 967 F.2d 980, 983 (4th Cir. 1992)). Relevant information in the discovery setting is different than in the evidentiary setting and, "need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.* at 7 (quoting Fed. R. Civ. P. 26(b)(2)(iii)). "Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party . . . ." *Id.* at 6; *See also Marks v. Global Mortgage Group, Inc.*, 218 F.R.D. 492 (S.D.W Va. 2003)(holding that similar transactions carried out by the defendant bank were relevant to the plaintiff's claims and as such were relevant and discoverable).

The manufacturing processes of the entire Little Falls plant are similar processes just as the bank transactions in *Marks* were similar transactions. As Anthony Delicato testified, every product line manufactured at the Little Falls plant is manufactured by the same limited group of machines; which machines are operated by the same group of personnel as Digitek® (Ex. C at 69:14-70:3). Therefore, an occurrence in the non-Digitek® processes is very likely to be similar and relevant to an occurrence within the Digitek® product line.

Rule 26 further grants authority to the courts to compel discovery of anything relevant to the "subject matter involved". *Taggart* at 6.(Quoting Fed. R. Civ. P. 26(b)(2)(i)). The testimony of Fitzpatrick and Delicato made clear that a supervisor at any given moment for the production of Digitek® would have been a supervisor for the production of a non-Digitek® product shortly before or shortly after the production of Digitek®, or, in some cases, the supervisor may be acting as a supervisor for Digitek® and another drug being manufactured at the exact same time. Thus it is likely that an incident that occurred during the production of one product would be

similar or even identical to an incident involving the production of Digitek®. Similarly, a supervisor or production employee's conduct and decision making process is not likely to change depending on what drug is being produced. Therefore, the *Taggart* relevancy standard of being related to the subject matter involved is easily met because the subject matter involved is the negligent manufacturing processes.

Further, as noted in the FDA warning letters that were sent in 2006 and 2007, several of the products produced at the Little Falls plant had deviations from manufacturing specifications. The same people operating the same machines were producing products that were out of specification—the exact allegation that is central to Plaintiffs' claims in the present litigation. These deviations from manufacturing specifications are clearly relevant to the present case as they will provide insight as to how and why the deviations in the manufacturing of Digitek® occurred. This information is directly relevant and material to the issues at stake in this litigation. As such the court must allow the Plaintiffs to engage in discovery as to all products manufactured at the Little Falls facility.

Defendants are expected to argue that discovery should not be broadened to include all drugs manufactured at the Little Falls facility because discovery for the other product lines will be unduly burdensome. If an objection arises that discovery has gone beyond relevant material, or that good cause does not exist, the resisting party bears the burden of showing why it is irrelevant, or unduly burdensome. *Newman v. Memphis Light Gas and Water*, 2009 U.S. Dist. LEXIS 504 (W.D. Tenn. 2009); *See also Fisher v. Borden, Inc.*, 1994 U.S. Dist. LEXIS 21275, 5 (D.N.J. 1994) (stating that the resisting party bears the burden of clarifying, explaining, and supporting its objections). Merely asserting that the discovery is overly burdensome is not

enough and affidavits or evidence as to the nature of the burden should be submitted as proof. *Smith v. Equifax Info. Svs., Inc.*, 2005 U.S. Dist. LEXIS 24742 (D. Conn. 2005).

Under the rules, facts are not discoverable if they are: (1) privileged, (2) unreasonably cumulative, (3) duplicative, or (4) fail a cost-benefits analysis. *Thompson v. Dept. of Housing and Urban Develop.*, 199 F.R.D. 168, 170 (D.Md 2001). With a cost benefit analysis, the burden associated with discovery and the benefit presented to the party seeking discovery is balanced with: (1) the needs of the case, (2) the amount in controversy, (3) the parties resources, (4) the importance of the issues at hand, and (5) how important said discovery will be to the resolution of the issues. *Id*. The cost benefit analysis would show that this new discovery would yield more benefit than cost to the parties. The testimony already shows that the manufacturing records are kept in the same fashion and in the same locations for all processes of the Little Falls facility. As such it would not be overly burdensome or costly to produce this information. On the other hand, the discovery sought will be infinitely valuable to the Plaintiffs understanding of the Digitek® manufacturing process and determination of how out-of-specification Digitek® made its way to the market.

CONCLUSION

Based on the forgoing reasons the stay on the Plaintiffs' subpoena should be lifted, and discovery should be expanded to include information relating to all manufacturing processes for all product lines produced at the Little Falls plant by the Actavis Defendants. In the alternative if the scope is not broadened, the Plaintiffs respectfully ask that this court be afforded a chance to review the original non-redacted documents to examine them for confidentiality under the rules set forth in the original PTO.

Dated: June 9, 2009

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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